IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff and Counterclaim Defendant,	)	
	)	
v.	)	C.A. No. 07-229 (GMS)
	)	
RANBAXY INC., and RANBAXY LABORATORIES LIMITED,	)	
	)	
Defendants and Counterclaim Plaintiffs.	)	

MERCK'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR LEAVE TO FILE ITS FIRST SUPPLEMENTAL COMPLAINT

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INTRODUCTION

Ranbaxy's opposition ignores that Merck's declaratory judgment counts are not based on causes of action arising from acts of infringement that have already occurred, but instead seek a declaration of rights as to future causes of action for acts of infringement that have yet to occur. Obviously no cause of action for infringement based on actual sales of Ranbaxy's ANDA product has yet arisen, because Ranbaxy has not yet made a single sale. Ranbaxy altogether ignores this critical distinction, and ends with the absurd result that, under *Southwest Software*, the '868 patent COC is ineffective for future acts of actual infringement under § 271(a), (b), or (c), even if no act of actual infringement has occurred. This position makes no sense. *Southwest Software* dealt only with acts of infringement occurring prior to the time the COC issued. Ranbaxy's position flatly contradicts the clear pronouncements in *Southwest Software* that a COC is effective "***at all times*** after its issue date" and that if a COC was necessary to overcome an invalidity problem, the "***invalidity ceased***" on the very day the COC issued. Further, Ranbaxy's argument ignores that Merck's declaratory judgment counts do not bar Merck from raising claims against Ranbaxy in the future once Ranbaxy begins to infringe the '868 patent by selling its ANDA product—for example, a separate future claim for damages based on those sales.

Ranbaxy's opposition is also flawed because it depends on the premise that multiple acts of patent infringement (e.g., multiple sales of an infringing product) constitute a single cause of action, rather than multiple causes of action. (D.I. 51 at 21-22). In other words, according to Ranbaxy, a series of actual infringing acts gives rise to only one cause of action. As shown below, even if this case involved continuing sales of an infringing product that had already begun, which it does not, Ranbaxy's argument would fail. The applicable Federal Circuit authority defining causes of action for patent infringement and the relevant case law on the

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language in the statute at issue here—"actions for causes thereafter arising"—establish unequivocally that multiple acts of infringement create multiple causes of action and a COC will apply to ***acts of infringement*** that occur after the COC is issued, whether or not acts of infringement also occurred before the COC issued.[1]

ARGUMENT

I. RANBAXY ERRONEOUSLY ARGUES THAT MERCK CONCEDED A PRE-COC PRIORITY DEFECT AND THAT RANBAXY RELIED ON THE ALLEGED DEFECT.

Before turning to the basic substantive flaws in Ranbaxy's argument, Merck addresses two points that Ranbaxy makes in the beginning of its argument. First, Ranbaxy states that "Merck admits that the '868 patent-in-suit issued without any claim to benefit under 35 U.S.C. § 120 of an application which it characterizes as a 'parent' application." (D.I. 51 at 9). Ranbaxy cites Merck's brief at page 3 for the alleged admission, but Merck's brief contains no such admission. Rather, on that page, Merck unequivocally stated the opposite: that its "primary position [is] that the error on the '868 patent has ***no effect on the priority date*** or validity of the '868 patent." (D.I. 49 at 3). Merck asserts that, even without the COC, the '868 patent is entitled to the benefit of the earlier parent application under 35 U.S.C. § 120.[2]

Ranbaxy also suggests that it relied on the alleged priority defect. (D.I. 51 at 11). Even if Ranbaxy did rely on the alleged defect, however, such reliance would not have been reasonable.

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[1] Ranbaxy attempts to disparage Merck and its counsel in Ranbaxy's "Counterstatement of Facts." Merck briefly addresses Ranbaxy's misstatements at the end of this brief, although Ranbaxy's improper charges are irrelevant to the issues presented.

[2] Ranbaxy relies on Merck's alleged admission to argue that, if the COC is inapplicable in the present action, the '868 patent claims are "anticipated by or obvious over" a September 1980 Abstract and poster session. Merck never made such an admission, nor would the claims be anticipated or rendered obvious over this alleged art without the COC. As noted above, the '868 patent is entitled to the filing date of the earlier parent application even without the COC. *Id.*

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The Federal Circuit in *Superior Fireplace Co. v. Majestic Prods. Co.*, 270 F.3d 1358, 1370-73 (Fed. Cir. 2001), addressed the issue of public notice in the context of corrections under 35 U.S.C. § 255, and noted that § 255 is a part of a "statutory scheme" that "reveals Congress' concern for public notice and for protecting the public from the unanticipated broadening of a claim." *Id*. at 1371. To protect the public from unanticipated broadened claims through corrections under § 255, the Federal Circuit required that the public be able to discern the error from the public file, including the prosecution history.

Here, the alleged defect and the subsequent correction did not involve any broadening of a claim, so public notice is not a concern. The '868 patent COC inserted references to the application number in the priority chain that was inadvertently omitted from the face of the '868 patent. This sort of "correction for the purpose of perfecting a claim for priority under 35 USC 120 does not change the scope of a patent." *In re Schuurs*, 218 U.S.P.Q. 443 (1983). Moreover, the alleged defect was fully discernible from the public record. Indeed, Ranbaxy pointed out the obvious error in its January 22, 2007 letter. (D.I. 52 at Ex. 1). And the prosecution history for the '868 patent shows the priority claim to the parent application at issue. Ranbaxy knew, or should have known, that the alleged error on the face of the '868 patent was correctable.

In fact, Ranbaxy's treatment of the alleged missing priority chain reference in its ANDA Notice letter suggests that Ranbaxy believed it to be at most a minor error. Ranbaxy's brief now attempts to suggest that the missing reference in the priority chain was a major ground of invalidity stressed in its Notice letter. That was simply not the case; it was mentioned only as an aside in a single paragraph in the introduction of the 27-page letter.

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II. RANBAXY'S IGNORES THAT MERCK SEEKS A DECLARATORY JUDGMENT REGARDING FUTURE ACTS OF INFRINGEMENT.

Throughout its brief, Ranbaxy ignores the critical distinction between, on the one hand, a request for a declaratory judgment regarding acts of infringement that have not yet occurred, and on the other, a claim based on a cause of action arising from infringement under § 271(a), (b), or (c) that has already occurred. Count I of Merck's original complaint and its proposed supplemental Counts III, IV, and V are ***declaratory judgment*** counts regarding acts of infringement that will occur in the future, and are not themselves claims based on ***causes of action*** arising from acts of infringement that have already occurred. At some point in the future when Ranbaxy begins to market and sell its ANDA product, Merck will have a cause of action for infringement under § 271(a), (b), or (c). Until Ranbaxy does so, no such cause of action for infringement can possibly have arisen.

Because Merck's cause of action for actual infringement under these provisions has yet to arise and will only arise in the future, the '868 patent COC is effective as to these future causes of action under the explicit provision in § 255 that a COC "shall have the same effect and operation in law on the trial of actions ***for causes thereafter arising***." 35 U.S.C. § 255. Further, the '868 patent COC is relevant to the declaratory judgment counts in this case because Merck seeks a declaration as to its rights under the '868 patent in the future regarding Ranbaxy's future infringement of that patent. This is dispositive of the issue in Merck's favor.

Merck's declaratory judgment counts seek a "prospective declaration" of the parties' rights as they exist at some time in the future when Ranbaxy begins to infringe, which obviously will occur only after the COC has issued. *Grace Holdings, L.P. v. Sunshine Mining & Ref. Co.*, 901 F. Supp 853, 857 (D. Del. 1995) ("The Declaratory Judgment Act, 28 U.S.C. § 2201, provides statutory authority for the federal courts to make ***prospective declarations*** regarding

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'the rights and other legal relations of any interested party seeking such declaration.'") (emphasis added). In resolving the parties' disputes implicated by Merck's declaratory judgment counts, this Court will be prospectively resolving Merck's future causes of action underlying its declaratory judgment count. *See, e.g., Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1330 (Fed. Cir. 2001) ("[I]t is the underlying cause of action of the defendant against the plaintiff that is actually litigated in a declaratory judgment action…").

Accordingly, it is not relevant whether Merck sued Ranbaxy for a declaratory judgment before the COC issued, or whether Merck waited until Ranbaxy actually begins to infringe by selling its ANDA product, which will occur only after the COC issued. Either way, at issue are the causes of action for Ranbaxy's infringing acts which will not occur until after the COC issued.

Ranbaxy attempts to blur the nature of the declaratory judgment counts that Merck brought, suggesting that Merck's declaratory judgment Count I is a claim for actual infringement under 35 U.S.C. § 271(a), (b) or (c). (D.I. 51 at 3, 22-23). But Count I contains no allegations of, and is not a cause of action for, actual infringement. Merck could make no such allegation because Ranbaxy has not yet infringed by selling its ANDA product. Thus, no cause of action for actual infringement under § 271(a), (b), or (c) has yet arisen. Merck simply sought a declaration that Ranbaxy's future sale of its ANDA product ***will infringe*** the '868 patent. (D.I. 1 at ¶ 16 ("Defendants' manufacture, use or offer for sale of the ANDA products… ***will*** constitute patent infringement…)).

A. *Southwest Software* Does Not Prevent Merck From Relying On The '868 Patent COC For Its Declaratory Judgment Counts.

Ranbaxy asks this Court to hold that a COC is not effective for a declaratory judgment count where actual infringement under § 271(a), (b), or (c) has not even begun to occur and will

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not begin until after the issuance of the COC. Tellingly, Ranbaxy cites no case under § 255 involving a declaratory judgment count concerning such future acts of infringement. *Southwest Software* did not involve such facts. *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280 (Fed. Cir. 2000). Rather, all the infringing acts had ceased prior to the issuance of the COC. Notably, neither *Southwest Software* nor any other case that Ranbaxy cites applying *Southwest Software* involved a declaratory judgment count.

Ranbaxy's attempt to apply *Southwest Software* to preclude Merck from relying on the '868 patent COC makes no sense. According to Ranbaxy, in light of *Southwest Software*, the '868 patent COC is ineffective even against acts of infringement that ***have not yet begun to occur***—namely, Ranbaxy's future sales of its ANDA product. To apply *Southwest Software* in this way would render meaningless the Federal Circuit's explicit pronouncement that the statute makes clear that a COC is considered to be part of the original patent "for all circumstances in which the certificate of correction is effective—namely, ***at all times*** after its issue date." *Southwest Software*, 226 F.3d at 1295. The Federal Circuit further elaborated that, "if claim 1 is found to have been invalid without the Program Printout Appendix, the ***invalidity ceased*** on April 1, 1997, ***when the PTO issued the certificate of correction***." *Id.* at 1297. In this case, the Court should find—consistent with *Southwest Software* and contrary to Ranbaxy's argument—that the COC applies to these future acts of infringement, as whatever invalidity existed before the COC ceased when it issued.

B. Merck's Declaratory Judgment Counts Do Not Bar Merck From Bringing A Later Action Against Ranbaxy.

Ranbaxy relies on *Polymer Indus. Prods. Co. v. Bridgestone/Firestone, Inc.* and says that Merck is "forever barred" from bringing any further action against Ranbaxy. (D.I. 51 at 30). Ranbaxy is wrong. In *Polymer*, the accused infringer sought a declaratory judgment of non-

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infringement for existing products, and the Court held that the patentee was obligated to bring a counterclaim of actual infringement. 347 F.3d 935, 938 (Fed. Cir. 2003). Merck seeks a declaratory judgment that Ranbaxy will infringe in the future and, as noted above, obviously could not have brought an action for actual infringement under § 271(a), (b), or (c), because no actual sales have occurred. That is the very reason Merck sought a declaratory judgment. Plainly, *Polymer* cannot "forever bar" Merck from bringing an action for actual infringement that has not yet occurred and which Merck therefore could not have brought earlier.[3]

That Merck sought a declaratory judgment regarding Ranbaxy's future infringement in no way prevents Merck from bringing a later action against Ranbaxy for damages, as Ranbaxy asserts. (*See* D.I. 51 at 30). The Restatement of Judgments sets forth the effect of a declaratory judgment ruling:

> A valid and final judgment in an action brought to declare rights or other legal relations of the parties is conclusive in a subsequent action between them as to the matters declared, and, in accordance with the rules of issue preclusion, as to any issues actually litigated by them and determined in the action.

Restatement (Second) of Judgments § 33. In a declaratory judgment action, "regardless of outcome, the plaintiff or defendant ***may pursue further declaratory or coercive relief in a subsequent action***." *Id*. at cmt. c. Thus, Merck would be entitled to bring an action for damages against Ranbaxy at some point in the future. *See, e.g., Edward B. Marks Music Corp. v. Charles K. Harris Music Publ'g Co.*, 255 F.2d 518, 522 (2d Cir. 1958) (allowing an infringement action and damages claim, following earlier declaratory judgment adjudication regarding ownership

[3] Ranbaxy also relies on *Polymer* to argue that "[e]ven if Merck had not alleged future infringement" then "any counterclaim relating to this cause of action would have been compulsory in Ranbaxy's counterclaim declaratory judgment action." (D.I. 51 at 29). Rule 13(a), however, requires only that "[a] pleading shall state as a counterclaim any claim which at the time of serving the pleading the pleader has against any opposing party." Fed. R. Civ. P. 13(a). This provision does not apply here, given that Merck could not have raised a counterclaim for actual infringement because Ranbaxy has not yet sold its ANDA product.

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rights as "further relief sought—here monetary recompense—need not have been demanded, or even proved, in the original action for declaratory relief."). Section 33 of the Restatement of Judgments actually provides an illustration of a declaratory judgment plaintiff seeking damages in a subsequent action. Restatement (Second) of Judgments § 33 Illus. 1.

Merck's claim for damages based on Ranbaxy's future infringement obviously has not yet arisen, since no sales have yet occurred.4 This claim for damages would not "necessarily be awarded in the present lawsuit under 28 U.S.C. § 2202, as 'further relief' based on a declaratory judgment of infringement," as Ranbaxy asserts (D.I. 51 at 29), since Merck can file a second action for such damages. Id. at cmt c; see also Alexander & Alexander, Inc. v. Van Impe, 787 F.2d 163, 166 (3d Cir. 1986) ("The language of the Declaratory Judgment Act itself indicates that a declaration as to the rights and obligations of the parties is not res judicata of a subsequent action for ***damages***.") (*citing Kaspar Wire Works, Inc. v. Leco Eng'g & Mach., Inc.*, 575 F.2d 530, 536-37 (5th Cir. 1978)).[5]

Indeed, Merck could bring a second action whether Ranbaxy wins or loses its invalidity argument regarding the '868 patent COC. As the Restatement makes clear, the effect of a declaratory judgment ruling is to render conclusive those matters that were "actually litigated." Restatement (Second) of Judgments § 33. "A plaintiff who has lost a declaratory judgment

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4 Similarly, Merck could not possibly have filed a claim for damages in connection with its Count II based on § 271(e)(2). *See, e.g., Eli Lilly v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Section 271(e)(4)(c) of the Hatch-Waxman Act specifically provides that "damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale…of an approved drug…."

5 In *Kaspar*, the Fifth Circuit addressed how *res judicata* principles apply to claims raised in an action filed after resolution of a declaratory judgment action. The court noted that "the Declaratory Judgments Act itself suggests the inappropriateness of applying rules of claim preclusion in the usual way," and that the Act "necessarily implies that a declaratory judgment does not embrace that aspect of res judicata known as merger" since "the prevailing party ***may seek further relief in the form of damages or an injunction***" in a later filed action. *Kaspar*, 575 F.2d at 536-37 (emphasis added).

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action may also bring a subsequent for other relief, subject to the constraint of the determinations made in the declaratory action." *Id*. at cmt. c. Consequently, even if Ranbaxy prevails in keeping out the COC and also prevails in invalidating the '868 patent without the COC, that "invalidity ceased…when the PTO issued the certificate of correction." *Southwest Software*, 226 F.3d at 1297. As a result, Merck would have a right to bring a second lawsuit alleging that sales by Ranbaxy after the COC issued infringe the valid '868 patent with the COC ***because the issue of validity with the COC would not have been litigated.***

III. RANBAXY'S ARGUMENT THAT MERCK HAS JUST ONE CAUSE OF ACTION IS WRONG—EACH ACT OF INFRINGEMENT IS A SEPARATE CAUSE OF ACTION.

Even if the situation here involved continuing sales of an accused product that had already begun, Ranbaxy's opposition would still fail, as each act of infringement—*i.e.*, each sale of Ranbaxy's ANDA product—gives rise to a separate cause of action. As Merck demonstrated in its opening brief (D.I. 49 at 7-8), Federal Circuit "case law clearly states that each act of patent infringement gives rise to a separate cause of action." *Hazlequist v. Guchi Moochie Tackle Co.*, 437 F.3d 1178, 1180 (Fed. Cir. 2006). Ranbaxy's argument to the contrary, that a single cause of action for infringement includes a series of separate acts, including continuing sales of an accused product, lacks merit and contradicts clear authority from the Federal Circuit. Ranbaxy's argument that the filing date of the lawsuit controls also lacks merit.

A. The Plain Language of 35 U.S.C. § 255 Does Not Speak To The Filing Of The Lawsuit, But To When Causes Of Action Arise.

Ranbaxy asserts that Merck should not be allowed to rely on the COC because Merck filed this litigation before it issued. Devoting almost a third of its brief to the applicability of a COC in relation to the timing of the filing of the lawsuit (D.I. 51 at 9-22), Ranbaxy conflates two independent concepts (cause of action and filing of a lawsuit) and apparently argues that the date

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the lawsuit is filed, not the date the cause of action arises, determines when a COC is applicable. In particular, Ranbaxy argues that "Merck's motion is nothing more than a transparent attempt to evade the consequences of its deliberate decision to file its complaint before seeking correction of its admittedly defective patent." (D.I. 51 at 1; *see also id*. at 12). The only way that there could be "consequences" to Merck's filing of its complaint would be if the date of filing of the complaint controlled whether the COC applied.

But Section 255 plainly states that a COC "shall have the same effect and operation in law on the trial of actions ***for causes thereafter arising***." 35 U.S.C. § 255. Section 255 does not state that a COC shall have the same effect and operation in law "on the trial of actions in ***lawsuits*** filed after issuance of the certificate of correction."

Further, *Southwest Software* does not support Ranbaxy's equating of the date of filing of a lawsuit with the time when a cause of action arises. As Merck pointed out in its opening brief, all of the infringing acts in *Southwest Software* occurred prior to the issuance of the COC, and no infringing acts occurred after, since shortly after the lawsuit was filed the defendant changed its product to the non-infringing "Revision 7." (D.I. 49 at 10). Thus, in *Southwest*, there was no substantive distinction between the time the lawsuit was filed and the time the cause of action for infringement arose, since both occurred before the COC issued.

B. The Federal Circuit's Post-*Southwest Software* Cases Under § 255 Do Not Adopt Ranbaxy's Bright-Line Test.

Although in *Southwest Software*, the Federal Circuit did not need to consider whether post-COC infringing acts give rise to new causes of action for which a COC would apply, Ranbaxy asserts that the case established a bright line test—a COC has no applicability to a lawsuit filed prior to the issuance of the COC, even for future acts of infringement because a single cause of action exists for continuing sales of a single product. (D.I. 51 at 12). The parties

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dispute the significance of *Southwest Software* in this regard, and there is no other Federal Circuit case squarely on point. Federal Circuit cases that deal with COC issues, however, demonstrate that Ranbaxy's bright-line test is wrong and that Merck's interpretation of *Southwest Software* is correct.

First, the Federal Circuit's decision in *Superior Fireplace* shows that the causes of action referred to in § 255 arise from individual acts of infringement, not entire lawsuits. In *Superior Fireplace*, even though the COC was sought because of arguments raised during litigation and issued (on August 17, 1999) months after the lawsuit was filed (on March 12, 1998), the Federal Circuit considered whether the COC was validly issued. 270 F.3d at 1364. If Ranbaxy's bright-line test were correct, the COC would simply have been inapplicable as to all alleged acts of infringement in *Superior Fireplace*, and there would have been no need to determine the validity of the COC. Rather than refusing to apply the COC to activities after the COC was issued (according to Ranbaxy's bright-line test), the majority in *Superior Fireplace* instead considered whether the COC was valid and whether application of the broadened claims of the COC patent would unfairly prejudice accused infringers by allowing the patentee to assert claims that were broader n scope than they were originally. *Id.* at 1366-76.

Although the dissent disagreed with the majority's imposition of the notice requirement in the prosecution history, the dissent reflected the same understanding that the COC applies to acts of infringement occurring after the COC issues, by (1) advocating to reverse the district court on the COC's validity and thereby apply the COC to the pending lawsuit and (2) explicitly stating that COC's are valid "for ***acts*** occurring after the certificate of correction issues." *Id*. at 1380 (emphasis added). Plainly, the judges in *Superior Fireplace* did not read *Southwest*

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Software as precluding applicability of a COC that issued after a lawsuit was filed. Otherwise, the discussion of the COC's validity and application would have been unnecessary.

Second, the Federal Circuit's decision in *Central Admixture* supports the same conclusion that *Southwest Software* did not establish a bright-line test that prohibited application of a COC to lawsuits filed prior to the COC. The Federal Circuit specifically noted that the COC issued "after the complaint in this lawsuit was filed." *Central Admixture Pharm. Servs. v. Advanced Cardiac Solutions P.C.*, 482 F.3d 1347, 1350 (Fed. Cir. 2007). The Federal Circuit also recognized that the district court applied the COC only to acts of infringement occurring after the COC issued, noting:

> [The district court] also granted to the plaintiffs conditional summary judgment of infringement and willfulness for actions occurring after the issuance of the certificate of correction, contingent upon the certificate being found valid. The district court later determined that the certificate was valid as a matter of law. The plaintiffs then withdrew their claims of infringement for acts prior to the issuance of the certificate,...

Id. at 1351-52. Rather than simply hold that the COC did not apply to the lawsuit at all, the Federal Circuit again considered whether the COC was valid, in particular to determine if the notice requirements of *Superior Fireplace* were met. *Id.* at 1353-55. As in *Superior Fireplace*, the discussion of the COC's validity would only be necessary if the COC could apply to "actions occurring after the issuance of the certificate of correction," just as the district court found.[6]

[6] Ranbaxy erroneously contends that the decision in *Central Admixture* was "*reversed in pertinent part*." (D.I. 51 at 20, emphasis original). The Federal Circuit did not disturb the holding that the COC was applicable to acts of infringement occurring after the COC. Instead, it reached the merits of whether the COC was valid and decided it was not. 482 F.3d at 1353-55.

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C. Ranbaxy's Interpretation Of "Actions For Causes Thereafter Arising" Conflicts With The Use Of The Phrase In The Reissue Statute.

Ranbaxy's interpretation of the statutory phrase at issue—"actions for causes thereafter arising"—conflicts with the Federal Circuit's interpretation of this same phrase in the context of 35 U.S.C. § 252, which concerns reissue patents. The phrase appears three times in Title 35, Chapter 25, Section 251-256, governing "Amendment and Correction of Patents"—once in each of §§ 252, 254 and 255, with § 252 relating to the effect of reissues and §§ 254 and 255 relating to certificates of corrections. Because Ranbaxy's argument is inconsistent with the interpretation of this statutory phrase in these other contexts, the Court should not adopt that interpretation. Under the "normal rule of statutory construction" as established by Supreme Court law, "identical words used in different parts of the same act are intended to have the same meaning." *Sorenson v. Sec'y of the Treasury*, 475 U.S. 851, 860 (1986).

The language "actions for causes thereafter arising" first appears in § 252, which relates to the effect of a reissue patent on future acts of infringement. Under Federal Circuit authority, this language requires application of the reissue patent on the day it issues to any individual act of infringement occurring on or after that date ***even where a claim for patent infringement was filed before reissue was granted.*** *Seattle Box Co. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 827-28 (Fed. Cir. 1984).

In *Seattle Box*, the lawsuit was filed July 2, 1980 and the reissue patent was issued August 19, 1980. *Id*. at 819-20. The Federal Circuit divided the period of potential liability into "two distinct time frames." *Id*. at 826. The first period was before the reissue patent issued; the second period "beg[an] on the date the reissue patent issued, August 19, 1980." *Id*. With respect to the time frame beginning on the issue date of the reissue patent, the Federal Circuit expressly considered the precise language at issue in this motion—"actions for causes thereafter arising."

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The Federal Circuit's analysis in *Seattle Box* shows that Ranbaxy's contention that a single cause of action exists for a series of infringing acts is simply wrong. If Ranbaxy were correct, the Federal Circuit would not have divided the infringement period into two time frames. The *Seattle Box* court would have simply held that the reissue could not apply to any acts of infringement in the *Seattle Box* case because the single cause of action arose before the reissue date. Instead, the Federal Circuit stated that the precise language at issue here from § 252 governed the second period of infringement—*i.e.*, all acts of infringement after the date of reissue for the same product ***in the same lawsuit*** as the acts that occurred before reissue. *Id*. at 829.

Because the identical language appears in §§ 254 and 255, it should be construed the same way as in *Seattle Box*, and Ranbaxy's contrary theory contradicts the "statutory scheme" enacted by Congress which includes § 255. *See Superior Fireplace*, 270 F.3d at 1370 (discussing § 255 as part of a "statutory scheme" that "encompasses 35 U.S.C. 251-256, which govern the amendment and correction of patents").

D. Federal Circuit Precedent Is Squarely Contrary To Ranbaxy's Theory That A Single Cause Of Action Exists.

Ranbaxy contends that "a single cause of action for infringement includes a series of separate acts, including continuing sales of a single product accused of infringing a single patent." (D.I. 51 at 21-22). But, the law is clear that "each act of infringement is deemed a separate claim." *A.C. Auckerman Co. v. R.L. Chaides Constr. Co*., 960 F.2d 1020, 1031 (Fed. Cir. 1992). Ranbaxy's position that "Merck has only a single cause of action for infringement of any ANDA product" is therefore wrong. (D.I. 51 at 31).

Ranbaxy relies on *Auckerman*, nevertheless, for the proposition that, "although patent infringement is a 'continuing tort,' such 'continuing tortuous acts may be deemed to constitute a

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unitary claim.'" (D.I. 51 at 32). But in *Auckerman*, the Federal Circuit considered only how to treat separate acts of infringement for purposes of laches. It explained that "laches has been viewed as a single defense to a continuing tort up to the time of suit, not a series of individual defenses which must be proved as to each act of infringement" and it is "***[t]o that extent***, [that] continuing tortious acts may be ***deemed*** to constitute a unitary claim." 960 F.2d at 1031. The Federal Circuit elsewhere has made clear that, although separate acts of infringement can be treated as a unitary claim for laches under *Aukerman*, they still give rise to separate causes of action. *Augustine Med., Inc. v. Progressive Dynamics, Inc.* 194 F.3d 1367, 1371-72 (Fed. Cir. 1999) ("[]Progressive's counter-argument is not on point because its assertion of continuing torts as a unitary claim is related to the doctrine of laches…."). As the Court stated in *Augustine*, under *Auckerman*, "issues of patent infringement ***do give rise to individual causes of action***." *Id.* at 1372.

Further, the Court in *Auckerman* only treated separate causes of action as a unitary claim for acts of infringement that accrued before the suit was filed. *Auckerman* explicitly held that "laches bars relief on a patentee's claim only with respect to damages accrued prior to suit," rather than bar all relief, including damages on acts of infringement that occur after suit was filed. 960 F.2d at 1041. As *Auckerman* explained, "[a]ll relief would generally be denied by a finding of laches if there is only a single wrong" but in the patent context, laches is "a partial defense" since there may be "future wrongs," *i.e.*, acts of infringement that occur after suit was filed. *Id.* Thus, *Auckerman* shows that even in the laches context, the patentee has not a single cause of action, but multiple causes of action in the case of continuing sales of a single infringing product.

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Ranbaxy's contention that *Hazlequist* does not suggest that "a patent owner may bring successive actions alleging infringement of the same patent, by the same product" misses the point. (D.I. 51 at 32). Under *Southwest*, the question is not whether the law of *res judicata* allows a patentee to bring a separate lawsuit in the future based on acts of infringement occurring after the COC issued. The question is whether a cause of action has arisen after the COC issued. Under *Hazlequist*, a new act of infringement, based on the same product, gives rise to a new cause of action. Indeed, *Auckerman* recognizes that "claim preclusion" is simply another exception where separate causes of action arising from separate acts of infringement can, in certain circumstances, be treated together (though claim preclusion does not apply here as already discussed). 960 F.2d at 1031.

Ranbaxy's other authority on claim preclusion likewise does not apply. First, *Young Engineers, Inc. v. Int'l Trade Comm'n*, 721 F.2d 1305 (Fed. Cir. 1983), considered whether multiple causes of action arising from multiple acts of infringement should be treated as a single claim for claim preclusion. 721 F.2d at 1316. *Aukerman* specifically cited *Young Engineers* in pointing out that separate causes of action can be treated as a unitary claim for purposes of claim preclusion. 960 F.2d at 1031. Thus, *Auckerman* makes clear that, under *Young Engineers*, separate acts of infringement give rise to separate causes of action, even if a second lawsuit would be barred by claim preclusion.

Second, the Restatement (Second) of Judgments says nothing about whether new acts of patent infringement give rise to separate causes of action; it does not even use the term "cause of action." Restatement (Second) of Judgments § 24. The Restatement, like *Aukerman*, simply recognizes that a "series" of related acts can be treated as one for the purpose of *res judicata* for "pragmatic[]" reasons.

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Third, *Mars, Inc. v. Kabushiki-Kaisha Nippon Conlux*, 58 F.3d 616, 619 (Fed. Cir. 1995), states merely that a patentee cannot "split a cause of action" and says nothing about whether new acts of infringement give rise to entirely new, separate causes of action. In *Mars*, the court held that a patentee could not sue one tortfeasor in a first case and then bring a second case against a second related tortfeasor for the same acts of infringement. *Id*. at 620.

Fourth, in *Alyeska Pipeline Serv. Co. v. United States*, 688 F.2d 765 (Ct. Cl. 1982), the plaintiff alleged breach of contract, not patent infringement or other continuing tort. That court made clear that such a breach of contract "normally gives rise to only one claim." *Id.* at 769.

E. None Of Ranbaxy's Cases On COCs Squarely Support Its Position.

Ranbaxy points to no case that squarely addresses the difference between application of a COC for activities that occur before the issuance of a COC as compared to activities that occur after issuance. As noted above, *Southwest Software* does not address this difference, as there is no dispute that there were no infringing activities that occurred after the COC issued in that case. Ranbaxy relies on *ISCO Int'l, Inc. v. Conductus, Inc.*, 2002 U.S. Dist. LEXIS 21706 (D. Del. Nov. 8, 2002), without challenging Merck's argument that the case did not address, and the patentee apparently did not present, the separate issue of whether a COC issued after a lawsuit is filed is effective for infringing activities that occur after the COC issues, even if the COC were ineffective for pre-COC infringing activities.

Similarly, none of the district court cases Ranbaxy cites involved declaratory judgment claims for future acts of infringement that have not yet begun to occur and none squarely addresses whether a COC applies to acts of infringement that occur after the COC issued:

- In *Rohm Co. v. Nichia Corp*., 2003 U.S. Dist. LEXIS 22227 (E.D. Pa. Nov. 26, 2003), the court did not discuss whether post-COC acts of infringement would be considered differently than pre-COC acts of infringement.

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- In *Electronic Planroom*, "the requested certificate of correction ha[d] not yet been issued." *Elec. Planroom v. McGraw-Hill Cos.*, 135 F. Supp. 2d 805, 827 (E.D. Mich. 2001). Consequently, all acts of infringement under consideration were necessarily before any COC was issued. The court relied on the patent owner's admission that the court was not permitted to treat the patent as corrected. *Id*.

- In *Adrain v. Hypertech, Inc.*, the issue similarly was not whether post-COC acts should be treated differently than pre-COC acts. The issue there was "whether the correction also applies *retroactively*." 2001 U.S. Dist. LEXIS 19182, at *13 (D. Utah April 18, 2001) (emphasis original). The patent owner in that case, unlike Merck, was attempting to have the COC apply to pre-COC activities. In any event, the case fails to discuss the issue presently before this Court.

- In *Rambus*, the court, in a footnote, merely noted that Rambus improperly asserted a patent having typographical errors. *Rambus, Inc. v. Infineon Techs. AG,* 155 F. Supp. 2d 668, 677 (E.D. Va. 2001). The court did not address whether a COC had even issued at all, much less whether post-COC acts are treated differently from pre-COC acts.

- In *STMicroelectronics*, the court expressly held that the relevant issue is when the cause of action arose, not when the lawsuit was filed. *STMicroelectronics, Inc. v. Motorola, Inc.,* 327 F. Supp. 2d 687, 699 (D. Tex. 2004). However, the parties never presented the issue of whether post-COC acts of infringement were causes of action that arose after the COC was issued and failed even to present sufficient evidence to the Court on the issue at all. In fact, the court stated it would reconsider the applicability of the COC if the parties submitted more evidence on the issue of when the cause of action arose. *Id*. at n.14.

- In *SDS USA*, the issue was not whether post-COC acts of infringement are treated differently than pre-COC acts of infringement. Instead, the issue was "whether this certificate of correction would apply retroactively." *SDS USA, Inc. v. Ken Specialties, Inc.*, 2002 U.S. Dist. LEXIS 16762 (D.N.J. 2002). The patent owner argued for retroactive application on the erroneous theory that § 255 should be treated differently than § 254 and did not distinguish pre- and post-COS acts. *Id.*

- And, once again, in *Mobile Hi-Tech*, *Karol* and in *Nova Measuring Instruments*, the courts' one-paragraph discussions of the applicability of a COC contain no discussion of the issue of whether there is any difference in the applicability of a COC to post-COC acts of infringement as compared to pre-COC acts of infringement. *Mobile Hi-Tech Wheels v. CIA Wheel Group*, 2007 U.S. Dist. LEXIS 68760 (C.D. Cal. Mar. 20, 2007), *Karol v. Burton Corp.*, 234 F. Supp. 2d. 450 (D. Vt. 2002), *Nova Measuring Instruments, Ltd. v. Nanometrics Inc.*, 2006 U.S. Dist. LEXIS 90736 (N.D. Cal. Dec. 1, 2006).

The only case to discuss this issue is *Central Admixture*, as discussed in Merck's opening brief (pp. 10-11). Ranbaxy claims that the logic of *Central Admixture* is "against the great weight of reasoned precedent" (D.I. 51 at 21), but as discussed above, the cases Ranbaxy cites do

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not even address the critical issue of whether a COC applies to acts of infringement that occur after a COC was issued. In contrast, the district court in *Central Admixture* addressed this precise issue and provided a thorough analysis of *Southwest Software* in that context. *Central Admixture Pharm. Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 2006 U.S. Dist. LEXIS 95833, at *56-61 (N.D. Ala. Jan. 10, 2006). Ranbaxy's argument that this case "has no precedential value" is unsound, since it is the logic reflected in *Central Admixture* that is compelling here. (D.I. 51 at 20). Moreover, as discussed above, the Federal Circuit's treatment of *Central Admixture* on appeal supports Merck's position, not Ranbaxy's.

IV. RANBAXY'S ATTACKS ON MERCK ARE UNWARRANTED.

Ranbaxy's "Counterstatement of Facts" alleges that Merck "surreptitiously filed" for and "secretly obtained a certificate of correction" and "improperly concealed its actions from Ranbaxy and the Court." (D.I. 51 at 10). Ranbaxy's disparagement is unwarranted.

Preliminarily, COC proceedings are *ex parte*, and Ranbaxy had no standing to participate in the proceeding. *See* MPEP § 1480 ("Third parties do not have standing to demand that the Office issue, or refuse to issue, a Certificate of Correction").

Moreover, Merck's handling of discovery was perfectly proper. In June 2007, Merck contacted Ranbaxy to inquire about the possibility of commencing broad-based discovery early. Merck also asked Ranbaxy to provide its ANDA materials and all communications to and from the FDA now so that Merck could have a better understanding of the timing of the FDA's review of Ranbaxy's application. Ranbaxy refused both requests. Thus, the parties did not start early, voluntary discovery before the scheduling conference on September 19.[7] On September 21,

[7] There was no reason for Merck to mention the COC at the scheduling conference, as Ranbaxy suggests, because the COC was not relevant to the setting of the schedule.

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2007, Merck served Ranbaxy with document requests, and on October 9, 2007 Ranbaxy served document requests on Merck. Although Merck's responses were not due until November 8, Merck agreed to begin document production on October 17, 2007 and produced its first set of documents containing file histories which had been obtained prior to Merck's request for a COC.

Two days later, on October 19, Ranbaxy requested that Merck "immediately provide copies of all papers Merck lodged at the PTO," which Ranbaxy claimed it was unable to obtain through public channels. (D.I. 52 at Ex. 17). The parties conducted a meet and confer at which Merck did not take the position that the COC proceedings were "confidential and not open to the public" as Ranbaxy alleges. (D.I. 52 at 8). Rather, Merck stated that it would look into whether the documents were confidential given Ranbaxy's representation that it had been unable to obtain them. (D.I. 52 at Ex. 11). Merck confirmed that the documents were not confidential and, the next day, produced the documents relating to Merck's request for a COC, well before its response to Ranbaxy's documents requests was due.

Finally, Ranbaxy was not prejudiced by receiving the COC documents a week and a half into discovery. Not only did it have no standing to participate in the COC proceeding, but the COC proceeding related to the correction of a minor typographical error in the '868 patent that was obvious to Ranbaxy (indeed, Ranbaxy had pointed it out to Merck in its letter of January 22, 2007) and to the PTO (which granted Merck the COC).

CONCLUSION

For the reasons set forth in Merck's Opening Brief and above, Merck's motion for leave to supplement its complaint should be granted.

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CERTIFICATE OF SERVICE

I hereby certify that on February 20, 2008, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

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Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on February 20, 2008 upon the following individuals in the manner indicated:

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